

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9093

Bartle, J.

June 20, 2013

The Estate of Kenneth L. Wright (the "Estate"), a representative claimant under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Emma L. Wright, Kenneth L. Wright's ("Mr. Wright" or "decedent") spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices
(continued...)

To seek Matrix Benefits, a representative claimant⁴ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the decedent's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In May, 2004, Ms. Wright, administratrix of Mr. Wright's Estate, submitted a completed Green Form to the Trust signed by decedent's attesting physician, Dominic M. Pedulla, M.D., F.A.C.C. Dr. Pedulla is no stranger to this litigation.

3. (...continued)

(Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimant's when the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators, or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

According to the Trust, he has signed in excess of 128 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated December 31, 2002, Dr. Pedulla attested in Part II of the Estate's Green Form that the decedent had severe mitral regurgitation and died as a result of a condition caused by VHD or valvular repair/replacement surgery.⁵ Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits in the amount of \$1,066,391.⁶

In the report of claimant's echocardiogram, Dr. Pedulla stated that Mr. Wright had "[s]evere mitral regurgitation - Doppler is technically limited; planimetry consistent with severe mitral regurgitation as best can be determined by limitations." Dr. Pedulla, however, did not specify a percentage as to Mr. Wright's level of mitral regurgitation. Under the Settlement Agreement, severe mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is greater than 40% of the Left Atrial Area ("LAA"). See Settlement Agreement §§ I.22 & IV.B.2.c.(2)(b). To satisfy the requirement under the Settlement Agreement that a claim for Matrix V benefits for death

5. Dr. Pedulla also attested that Mr. Wright had an abnormal left atrial dimension and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a representative claimant is entitled to Level V benefits if the decedent suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records."

resulting from a condition caused by valvular heart disease be "supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records," the Estate included with its Green Form an April 28, 2004 letter from Dr. Pedulla. Dr. Pedulla opined that "it is probable that the condition resulting in [Mr. Wright's] death was caused by his valvular heart disease."

In May, 2005, the Trust forwarded the claim for review by Donna R. Zwas, M.D., F.A.C.C., one of its auditing cardiologists.⁷ In audit, Dr. Zwas determined that there was no reasonable medical basis for Dr. Pedulla's finding that the decedent suffered from severe mitral regurgitation. Dr. Zwas explained, "The mitral regurgitation seen on this study is physiologic or at most mild. The bluejet planimetered during the study represents flash artifact and is not representative of the regurgitation." Dr. Zwas also concluded that there was no reasonable medical basis for Dr. Pedulla's finding that the decedent died as a result of a condition caused by valvular heart disease. Dr. Zwas determined:

Death resulted from congestive heart failure and heart dysfunction in the setting of an ischemic cardiomyopathy. The patient had multiple heart attacks in the 3 years prior to his death, and had refused further revascularization. As he had no significant

7. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that the Estate had a Matrix A-1, Level V claim, the Trust audited the Estate's claim pursuant to the PPP.

valve disease, it did not contribute to his death.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the Estate's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁸ In contest, the Estate submitted two letters from Dr. Pedulla wherein he reaffirmed his findings of severe mitral regurgitation and death resulting from a condition caused by VHD. In the first letter, Dr. Pedulla stated that there was a reasonable medical basis for his representation that Mr. Wright's December 31, 2002 echocardiogram demonstrates severe mitral regurgitation because it was consistent with a number of other echocardiograms submitted, including one performed in the Trust's Screening Program.⁹ Relying on these additional echocardiograms, Dr. Pedulla stated the planimetered jet is representative of regurgitation and that it is not improperly traced. Dr. Pedulla also disputed the conclusion of Dr. Zwas that Mr. Wright did not die as a result of a condition caused by VHD. He explained:

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

9. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

The December 31st, 2002 echocardiograms showed severe mitral regurgitation as well as good left ventricular function. The patient at that time already had attained functional class III, indicating severe congestive heart failure, yet without evidence of myocardial infarction or regional wall motion impairment, which normally would have been found should "ischemic cardiomyopathy" have been the culprit. Therefore, I do not believe the auditor was correct about the assessment of "ischemic cardiomyopathy."

In the second letter, Dr. Pedulla contended that the auditing cardiologist's finding that Mr. Wright did not die as a result of a condition caused by VHD was subjective and arbitrary because he believes she only reviewed Mr. Wright's December 31, 2002 echocardiogram and he could not determine which of Mr. Wright's medical records Dr. Zwas actually reviewed. Based on this letter, the Estate argues that the audit by Dr. Zwas was incomplete and invalid.¹⁰

The Trust then issued a final post-audit determination again denying the claim. The Estate disputed this final determination and requested that the claim proceed to the Show Cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On November 20, 2006, we issued an Order to show cause and referred

10. The Estate also incorporated by reference a "pleading" of Class Counsel submitted in MDL 1203 that questioned the integrity of the Trust's audit process in connection with certain claims. As the Estate does not explain how this motion would impact, if at all, these proceedings, it is irrelevant to our disposition.

the matter to the Special Master for further proceedings. See PTO No. 6696 (Nov. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its Statement of the Case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on June 1, 2007, and the Estate submitted a sur-reply on June 21, 2007.

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹¹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution is whether the Estate has met its burden of proving that there is a reasonable medical basis for the claim. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in the Estate's Green Form that are at issue, we must

11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate asserts the same arguments it made in contest. In addition, the Estate also includes a summary of the medical records submitted with the claim. The Estate also contends that a "strict construction" of the requirement in the Settlement Agreement that the statement in support of death resulting from a condition caused by VHD be made by an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist would deny otherwise compensable claims. In further support of its claim, the Estate submits affidavits from Ms. Wright and Dr. Pedulla. In her affidavit, Ms. Wright stated that she requested that Dr. Pedulla "see and treat" Mr. Wright, but he died before Dr. Pedulla could see him. In his affidavit, Dr. Pedulla confirmed that he "did not assume the care and treatment of Mr. Wright." Dr. Pedulla also stated that, although Mr. Wright's death occurred before he could see him, Dr. Pedulla, a Board-Certified Cardiologist, considers himself one of Mr. Wright's attending physicians.

In response, the Trust asserts that the Estate has failed to establish a reasonable medical basis for its claim. With respect to Mr. Wright's level of mitral regurgitation, the

Trust argues that the Estate cannot establish a reasonable medical basis for Dr. Pedulla's representation based on the December 31, 2002 echocardiogram by reference to other echocardiograms. The Trust also contends that the measurements upon which Dr. Pedulla relied include artifact and are not representative of mitral regurgitation and that Dr. Pedulla's statement does not rebut the finding of Dr. Zwas but merely reaffirms Dr. Pedulla's prior finding. With respect to whether Mr. Wright died as a result of a condition caused by VHD, the Trust argues that the Estate has not submitted the statement of an attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist as required by the Settlement Agreement. The Trust also asserts that Dr. Pedulla's statement is not supported by Mr. Wright's medical records because:

(1) Mr. Wright's death certificate and death summary make no mention of VHD; (2) Mr. Wright's attending physician at the time of his death was a nephrologist, which indicates his death was caused by end stage renal disease rather than valvular heart disease; (3) Dr. Pedulla's conclusion that Mr. Wright did not die from an ischemic cardiomyopathy because there was no evidence of myocardial infarction is contradicted by Mr. Wright's death summary, which specifically mentions "acute myocardial infarction," and by an echocardiogram performed on January 12, 2004, which demonstrated an ejection fraction of 40%, evidence Mr. Wright did not have "good left ventricular

function"; and (4) Dr. Zwas reviewed all of Mr. Wright's medical records in reaching her conclusion.

In its sur-reply, the Estate argues that the Trust incorrectly argues that the Estate must prove "death caused by valvular heart disease" rather than "death resulting from a condition caused by valvular heart disease." The Estate asserts that the only question for the Technical Advisor is whether the echocardiogram demonstrates moderate or greater mitral regurgitation because Dr. Zwas based her opinion that Mr. Wright did not die as a result of a condition caused by VHD on the fact that Mr. Wright did not have significant valve disease. For this reason as well, the Estate contends that it was inappropriate for the Trust to refer to Mr. Wright's death certificate and death summary. In further support of its claim, the Estate submitted another letter from Dr. Pedulla, wherein he stated that

(1) Dr. Zwas incorrectly determined that the December 31, 2002 echocardiogram demonstrated at most mild mitral regurgitation and that it was improperly planimetered to include flash artifact; (2) Dr. Zwas did not provide an RJA/LAA ratio in connection with her review; (3) Dr. Zwas and he agreed that Mr. Wright died from congestive heart failure and that he believes that Mr. Wright's mitral regurgitation caused his congestive heart failure; (4) he is in a better position to assess Mr. Wright's condition because he was the attending physician and he reviewed all of the decedent's medical records; (5) the ejection fraction of 40% on the January 12, 2004 echocardiogram does not support a finding of

an ischemic cardiomyopathy; and (6) the characterization of myocardial infarction is strictly subjective and known to be inaccurate.

The Technical Advisor, Dr. Burke, reviewed the entire show cause record and concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Wright suffered from severe mitral regurgitation.

Specifically, Dr. Burke found that:

By visual inspection, my assessment of the degree of mitral regurgitation on the study of December 31, 2002 is that the mitral regurgitation is trace. The regurgitant jet area planimetered on the recording does not represent mitral regurgitation. This is clearly a flash artifact and is in no way related to the trace amount of mitral regurgitation noted.

I then calculated a regurgitant jet area (RJA) to left atrial area (LAA) ratio in the views provided. I would note that in many of the beats in all views, no mitral regurgitation was noted. In the parasternal long axis view, I calculated a RJA/LAA ratio of 2.8%. In the apical four chamber view, I calculated a RJA/LAA ratio of 3.4%. In the apical two chamber view, I calculated a RJA/LAA ratio of 3.8%. These values are all in the range of trace mitral regurgitation and would concur with my overall visual assessment of the degree of mitral regurgitation on this study. The subcostal view with color flow Doppler was technically limited and did not provide adequate images to assess a RJA/LAA ratio.

Dr. Burke also determined that there was no reasonable medical basis for Dr. Pedulla's finding that Mr. Wright died as a result of a condition caused by VHD. In particular, he explained:

The patient had a subsequent hospitalization in December of 2003 for a recurrent episode of non-ST segment elevation myocardial infarction. His troponin levels were significantly elevated during this hospitalization with readings of 15.4, 35.1, and 22.7 (top normal being 0.04). This would imply extensive myocardial damage. An echocardiogram done during this hospitalization was again technically difficult, but suggested that the mitral valve was "functioning properly by Doppler". The patient was readmitted to the hospital on January 12, 2004. The admission note described three hospitalizations for myocardial infarction in the last two years, the most recent one being December 2003. Neither the history and physical nor the cardiac consultation mentioned mitral regurgitation in the assessment of problem list. There was an absence of physical exam findings for moderate or severe mitral regurgitation. No mention is made of a brisk carotid up-stroke or the presence of a heart murmur. A nuclear scan shows a dilated left ventricle with global hypokinesis, especially involving the septum. The calculated left ventricular ejection fraction was 32.5% (normal 55% or greater). On January 15, 2004, the patient had a drop in blood pressure associated with a rise in pulse rate to the 150's with recurrent chest pain and hypoxia. The patient was a "do not resuscitate". Supportive measures were administered, but the patient expired. The discharge summary lists discharge diagnoses as acute myocardial infarction, wide complex tachycardia, end stage renal disease on dialysis, congestive heart failure, febrile, diabetes mellitus type II uncontrolled, and continuing chest pain. His death certificate lists renal failure, diabetes mellitus type II, ASCVD (arteriosclerotic cardiovascular disease). No mention is made of valvular heart disease on the January 2004 discharge summary or death certificate.

Based on the documents included in the record, the Claimant's death resulted from advanced and extensive atherosclerotic coronary artery disease. He had been deemed

inoperable in 2002. He had a long history of coronary artery disease. He suffered recurrent myocardial infarctions. He had recurrent episodes of chest pain including during the hospitalizations of December 22, 2003 and January 2004 leading to his death. He had significant elevations of his troponins indicating myocardial injury with his hospitalization in December 2003. No mention is made in the hospital records that valvular pathology or mitral regurgitation played a significant role in the patient's clinical course, or led to his cause of death.

The Estate submitted a response to the Technical Advisor Report, arguing that Dr. Burke should have been provided tapes of the six other echocardiograms and the color photographs of decedent's swollen feet and ankles. In addition, the Estate contends that swollen feet and ankles are an acknowledged symptom of mitral valve damage.

After reviewing the entire show cause record, we find that the Estate is not eligible to receive Matrix Benefits based on the echocardiogram of attestation. A claimant must satisfy the eligibility requirements set forth in Section IV.B.1.a. of the Settlement Agreement. The Settlement Agreement states that the following Class Members are eligible to receive Matrix Benefits:

Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement defines FDA Positive, in pertinent part, as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, to be eligible to seek Level V Matrix Benefits, the Estate must establish that Mr. Wright suffered from at least mild mitral regurgitation after he ingested Diet Drugs.

The Estate has not established that there is a reasonable medical basis for the attesting physician's finding that Mr. Wright suffered from severe mitral regurgitation. Contrary to the Estate's assertion, the letters from Dr. Pedulla do not establish a reasonable medical basis for his opinion that Mr. Wright's December 30, 2002 echocardiogram demonstrated severe mitral regurgitation. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than the Estate contends. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation;

(7) failing to take a Diet Drug Recipient's medical history; and
(8) overtracing the amount of a Diet Drug Recipient's
regurgitation. See PTO No. 2640 at 9-15, 21-22, 26.

Here, Dr. Zwas determined that "[t]he mitral regurgitation seen on [Mr. Wright's December 30, 2002 echocardiogram] is physiologic or at most mild." In support of her conclusion, she observed that "[t]he bluejet planimetered during the study represents flash artifact and is not representative of the regurgitation." Although Dr. Pedulla disagreed with Dr. Zwas, the Technical Advisor reviewed the December 30, 2002 and found that it demonstrated only trace mitral regurgitation. Dr. Burke explained, "The regurgitant jet area planimetered on the recording does not represent mitral regurgitation. This is clearly a flash artifact and is in no way related to the trace amount of mitral regurgitation." Although the Estate responded to the Technical Advisor, it did not specifically challenge Dr. Burke's analysis of the level of mitral regurgitation demonstrated by the December 30, 2002 echocardiogram or the deficiencies Dr. Burke identified with the measurements on the study. Such an unacceptable practice by the Estate's attesting physician cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

We also reject the Estate's assertion that the six other echocardiograms establish a reasonable medical basis for Dr. Pedulla's representation of severe mitral regurgitation based on the December 30, 2002 echocardiogram. As the echocardiogram

of attestation demonstrates only trace mitral regurgitation, the Estate's argument that the six other echocardiograms are relevant effectively is asking this court to simply substitute the original echocardiogram of attestation with six additional echocardiogram reports.¹²

Moreover, the Estate's argument that the opinion of Dr. Zwas should be disregarded because she did not provide an RJA/LAA ratio in connection with her review is without merit. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify for Matrix Benefits, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See id. at 15. The Estate essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision, and the Estate's contention is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.¹³

Finally, the Estate's argument that there is a reasonable medical basis for Dr. Pedulla's representation of

12. If otherwise permitted under the Settlement Agreement, the Estate may submit an additional Green Form to the Trust based on a different echocardiogram.

13. In any event, Dr. Burke measured Mr. Wright's RJA/LAA as less than 4%.

severe mitral regurgitation based on the December 30, 2002 echocardiogram because a December 31, 2001 echocardiogram obtained through the Screening Program was found to be diagnostic of moderate mitral regurgitation is misplaced. The Settlement Agreement clearly provides that the sole benefit which a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Settlement Agreement, § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Although a claimant may rely on an echocardiogram performed in the Screening Program to establish eligibility for or entitlement to Matrix Benefits, the echocardiogram must still pass audit. Adopting a contrary position would be inconsistent with the Settlement Agreement's provisions governing the audit of claims for Matrix Benefits (Settlement Agreement, § VI.E.) as well as this court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. Id. at 13. In that PTO, we held that "good cause

exists under the Settlement Agreement to modify the Trust's procedures to order it to designate all Fund B claims for audit." As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate eligibility for Matrix Benefits, we decline to interpret the Settlement Agreement in this fashion.

We also disagree with the Estate that there is a reasonable medical basis for Dr. Pedulla's representation that Mr. Wright died as a result of a condition caused by VHD. In his statement, Dr. Pedulla opines that "it is probable that the condition resulting in [Mr. Wright's] death was caused by his valvular heart disease." We have previously held that such an equivocal statement is insufficient to qualify a representative claimant to Level V Matrix Benefits. See, e.g., PTO No. 8444 (Mar. 31, 2010).

In addition, there does not appear to be a dispute that Mr. Wright's death resulted from congestive heart failure. Dr. Pedulla contends Mr. Wright's congestive heart failure was caused by his significant mitral regurgitation. Dr. Zwas reviewed Mr. Wright's medical records and determined that Mr. Wright's "heart dysfunction [was] in the setting of an ischemic cardiomyopathy" rather than as a result of VHD because Mr. Wright had minimal, if any, mitral regurgitation. Dr. Pedulla disputed that Mr. Wright's congestive heart failure was the result of an ischemic cardiography because he did not

find "evidence of myocardial infarction or regional wall motion impairment, which normally would have been found should 'ischemic cardiomyopathy' have been the culprit." The Trust pointed out that Mr. Wright's death certificate and death summary make no mention of VHD but did specifically mention "acute myocardial infarction." Dr. Burke also reviewed Mr. Wright's medical records and determined that there was evidence of myocardial infarction and that Mr. Wright had a properly functioning mitral valve. Dr. Burke explained, "He had significant elevations of his troponins indicating myocardial injury with his hospitalization in December 2003. No mention is made in the hospital records that valvular pathology or mitral regurgitation played a significant role in the patient's clinical course, or led to his cause of death." Thus, Dr. Burke concluded there was no reasonable medical basis for Dr. Pedulla's statement that Mr. Wright's death resulted from a condition caused by VHD. Based on our review of the entire record, we find that there is no reasonable medical basis for Dr. Pedulla's representation that Mr. Wright died as a result of a condition caused by VHD.¹⁴

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for the attesting physician's finding that Mr. Wright had at least mild mitral regurgitation based on the

14. Given our disposition, we need not determine whether Dr. Pedulla's statement constitutes a statement of Mr. Wright's Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist.

echocardiogram of attestation or that Mr. Wright died as a result of a condition caused by VHD. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix Benefits and the derivative claim submitted by Mr. Wright's spouse.